Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
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MAR 2 8 2001

BARD

Opti-Flow Long-Term Dialysis Catheter

510(k) Summary of Safety and Effectiveness Information
21CFR 807.92

1. Submitter Information:

Submitter Name:	Bard Access Systems, Inc. [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 4903
Fax Number:	(801) 595 5425
Contact Person:	Peggy Keiffer
Date of Preparation:	February 22, 2001

2. Device Name:

Device Name:	Opti-Flow®Long-Term Dialysis Catheter
Trade Name:	Opti-Flow®
Common/Usual Name:	Hemodialysis Catheter, Long-Term Intravascular Catheter
Classification Name:	78MSD Catheter, Hemodialysis, Implanted 21 CFR 876.5540 (b)(1) Class III Implanted Blood Access Device
Classification Panel:	Gastroenterology and Renal

3. Predicate Device Name:

Device Name:	Opti-Flow®Long-Term Dialysis Catheter
Trade Name:	Opti-Flow®
Common/Usual Name:	Hemodialysis Catheter, Long-Term Intravascular Catheter
Classification Name:	78MSD Catheter, Hemodialysis, Non-implanted 21 CFR 876.5540 – Implanted Blood Access Device
Classification Panel:	Gastroenterology and Renal

4. Device Description:

The device description of the subject Opti-Flow Long-Term Dialysis Catheter is as follows.

- The Opti-Flow Catheter is available in 14.5 French straight and precurved configurations. The insertion lengths are as follows:
  Straight: 15, 19, 23, 27, and 35 centimeters
  Precurved: 15, 19, 23, and 27 centimeters
- The Opti-Flow Long-Term Dialysis Catheter is made from soft polyurethane and contains barium sulfate to provide radiopacity.
- The shaft is circular with a "double D" dual lumen cross sectional design. The venous "D" lumen extends beyond the arterial lumen exit site to form a rounded venous tip and ends with a 45° bevel. Both lumen tips have two side holes.
- Acetal luer connectors identify the arterial (red) and venous (blue) lumens.
- The extension legs are made from polyurethane. Each extension has an atraumatic acetal clamp, which closes the access to the catheter.
- A removable suture wing is provided to place on the shaft near the exit site for securing the catheter after initial placement.
- A fixed retention cuff is located on the shaft to provide an anchoring site for tissue in-growth. The catheter is available with and without a VitaCuff® Antimicrobial Cuff positioned on the shaft between the retention cuff and the bifurcate.
- The catheter insertion length is printed on the bifurcation and the priming volumes are printed on the extension legs.

5. Intended Use:

The intended use of the OptiFlow Long-Term Dialysis Catheter is attaining short-term or long-term vascular access for hemodialysis, hemoperfusion, or apheresis therapy via the jugular or subclavian vein.

6. Technological Characteristics Summary:

6.1 Does the new device have the same indication statement?

Yes.

6.2 Does the new device have the same technological characteristics, eg. design, material, etc.?

Not in all respects. The principles of operation and basic design are equivalent. The blue and red polyvinylchloride (PVC) luer connectors are being replaced with acetal luer connectors. The catheter remains the same in all other respects. The acetal luer connectors are the same as those used on long-term Hickman Catheters for many years.

6.3 Could the new characteristics affect safety or effectiveness?

Yes. The integrity of the extension-connector interface could affect the safety or effectiveness of the device.

6.4 Do the new characteristics raise new types of safety and effectiveness questions?

No. The safety and effectiveness questions are the same for all long-term dialysis catheters.

6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95, and corresponding ISO Standards were used to evaluate the device's performance.

Biocompatibility meets the requirements of ISO-10993, " Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and the FDA Modified ISO 10993 Test Profile for externally communicating blood contacting long term devices.

6.6 Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the above referenced standards. The test results met the requirements and were compared to the predicate device.

6.7 Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the Opti-Flow Long-Term Dialysis Catheter with acetal luer connectors is substantially equivalent to the predicate Opti-Flow Long-Term Dialysis Catheter with PVC luer connectors.

6.8 Performance Data (if applicable).

Catheter guidance tests performed (only those test applicable to the luer connection) per *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
Dimensions
Tensile strength of catheter body to hub attachment
[For this project, extension leg to hub attachment]
Leakage at hub *[aspiration and infusion]*
Catheter burst pressure *[positive internal pressure]*

Catheter guidance tests NOT required for this product change:
Tensile strength of catheter body
Catheter stiffness
Catheter tip (distal) attachment strength
Catheter elongation
Catheter Collapse (negative internal pressure)
Catheter flexural fatigue tolerance

Flow rates, recirculation, hemolysis, biocompatibility and sterilization issues were considered under design controls, and no testing was required.

The Opti-Flow Long-Term Dialysis Catheters with new luer connectors meet all the performance criteria of the tests performed and, based on FDA's decision tree, are substantially equivalent to the predicate device, the Opti-Flow Long-Term Dialysis Catheters, K981994, concurrence date September 3, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2001

Ms. Peggy Keiffer
Regulatory Affairs Manager
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UTAH 84116

Re: K010567
Opti-Flow® Long-Term Dialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulatory Class: III/Product Code: 78 MSD
Dated: February 22, 2001
Received: February 26, 2001

Dear Ms. Keiffer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be

aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains PVP swabsticks and xylocaine which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director
Division of Reproductive, Abdominal
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section I-D

Opti-Flow Long-Term Dialysis Catheter

Special 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Regulatory Affairs Manager of Bard Access Systems, that this notification [510(k)] for the following devices, Opti-Flow Long-Term Dialysis Catheters, are indicated for the following:

The Opti-Flow dual lumen hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein.

Signature of 510(k) Submitter: Peggy Keiffer

Printed Name of Submitter: Peggy Keiffer

Date: February 6, 2001

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K010567

Division Sign-Off See below
Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use _____

David G. Hyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010567